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Effects on instruments of the World Health Organization-recommended protocols for decontamination after possible exposure to transmissible spongiform encephalopathy-contaminated tissue[†]

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KEYWORDS

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ABSTRACT

It has been recommended by the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) that rigorous decontamination protocols be used on surgical instruments that have been exposed to tissue possibly contaminated with Creutzfeldt-Jakob disease (CJD). This study was designed to examine the effects of these protocols on various types of surgical instruments. The most important conclusions are: (1) autoclaving in 1 *N* NaOH will cause darkening of some instruments; (2) soaking in 1 *N* NaOH at room temperature damages carbon steel but not stainless steel or titanium; (3) soaking in chlorine bleach will badly corrode gold-plated instruments and will damage some, but not all, stainless-steel instruments, especially welded and soldered joints. Damage became apparent after the first exposure and therefore long tests are not necessary to establish which instruments will be damaged. © 2004 Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater

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INTRODUCTION

Transmissible spongiform encephalopathies (TSEs) comprise a group of diseases that include Creutzfeldt-Jakob Disease (CJD) in humans, bovine spongiform encephalopathy (BSE or mad cow disease) in cattle, and scrapie in sheep.[1] The infectious agents (prions) found in these diseases are very difficult to destroy. They are not completely inactivated by conventional sterilization methods such as steam autoclaving (even at elevated temperatures) or by ethylene oxide gas.[2-6] Transmission of CJD in humans and animals by contaminated instruments has been demonstrated, but the devices were not subjected to modern cleaning, disinfection, and sterilization methods.[7-9] In the absence of any scientific study demonstrating successful decontamination, there is a growing public health concern regarding the spread of the disease by potentially contaminated surgical or dental instruments subjected to standard hospital cleaning and sterilization protocols.

The World Health Organization (WHO) has recommended the instruments be incinerated. However, because some instruments are expensive, WHO has suggested some stringent cleaning procedures for potentially prion-contaminated instruments before routine cleaning and sterilization if they are to be reused. The Centers for Disease Control and Prevention (CDC) has recommended on its web site[3] the most stringent WHO procedures should be considered:

1. Immerse in a pan containing 1*N* sodium hydroxide (NaOH) and heat in a gravity displacement autoclave at 121°C for 30 min; clean; rinse in water; and subject to routine sterilization. [CDC NOTE: The pan containing sodium hydroxide should be covered, and care should be taken to avoid sodium hydroxide spills in the autoclave. To avoid autoclave exposure to gaseous sodium hydroxide condensing on the lid of the container, the use of containers with a rim and lid designed for condensation to collect and drip back into the pan is recommended. Persons who use this procedure should be cautious in handling hot sodium hydroxide solution (postautoclave) and in avoiding potential exposure to gaseous sodium hydroxide, exercise caution during all sterilization steps, and allow the autoclave, instruments, and solutions to cool down before removal.]
2. Immerse in 1*N* NaOH or sodium hypochlorite (20,000 ppm available chlorine) for 1 h; transfer instruments to water; heat in a gravity displacement autoclave at 121°C for 1 h; clean; and subject to routine sterilization. [CDC NOTE: Sodium hypochlorite may be corrosive to some instruments.]
3. Immerse in 1*N* NaOH or sodium hypochlorite (20,000 ppm available chlorine) for 1 h; remove and rinse in water, and then transfer to open pan and heat in a gravity displacement (121°C) or porous load (134°C) autoclave for 1 h; clean; and subject to routine sterilization. [CDC NOTE: Sodium hypochlorite may be corrosive to some instruments.]

The CDC added cautionary notes indicating risks associated with these procedures. The issue of note under method 1 has been addressed previously.[10] The purpose of the present study was to address the instrument damage issues.

METHODS AND MATERIALS

Decontamination

To investigate the effects of the various steps in these protocols, five separate protocols were used:

- A Autoclave in 1*N* NaOH at 121°C for 60 min, followed by a 30-min rinse in ASTM 1 purified water in the ultrasonic cleaner, and dry with a towel. To contain the caustic vapors,[10] instruments were placed in a Nalgene pipet sterilizing pan with lid (Nalge Co., Rochester NY). This was repeated for 5 cycles.
- B Soak for 1 h in 1*N* NaOH at room temperature, followed by a 30-min rinse in ASTM 1 water in the ultrasonic cleaner, and dry. This was repeated for 5 cycles.
- C Soak for 1 h at room temperature in household bleach (5.25 or 6% sodium hypochlorite), followed by a 30-min rinse in ASTM 1 purified water in the ultrasonic cleaner, and dry. This was done until damage was observed or it had been done for 5 cycles.
- D Autoclave at 121°C for 60 min in water, in a dry stainless-steel pan with a lid, or in a pan wrapped in a towel. Care was taken to dry them after each run. This was repeated for 5 cycles.
- E Place in detergent in the ultrasonic cleaner at 60°C for 30 min followed by a 30-min ultrasonic treatment in ASTM 1 water. The instruments were not dried after the first run but were left on the bench. In the subsequent two runs they were dried after the rinse.

All autoclaving was done in a Harvey SterileMax bench top gravity displacement steam sterilizer (Barnstead Thermolyne, Dubuque, IA). All ultrasonic cleaning was done at 60°C in a Branson model 3510 (Branson, Danbury, CT).

Instruments

A selection of surgical instruments to encompass various materials and complexities was purchased from Roboz Surgical (Gaithersburg, MD). These included surgical scissors, several spreaders, hemostats, needle holders, tubing clamps, and a variety of tweezers by Dumont of Switzerland. All were stainless steel except for one type of tweezer made of carbon steel and one type made of titanium. Upon receipt it was noticed that some instruments were marked *Roboz Germany* and some were marked *Pakistan*, although the same catalogue number was used. A selection of less expensive stainless instruments was purchased from a laboratory supply house (VWR). These instruments were either not labeled, or they were labeled *Pakistan*.

Electrodes

Tungsten, platinum-iridium, and bipolar neurosurgical recording electrodes were purchased from Stoelting (Wood Dale, IL). They were subjected to room-temperature protocols B (NaOH), or C (bleach).

Examination

The instruments were observed after each treatment cycle. Those with apparent damage were examined under magnification. Those showing extreme damage were removed and did not undergo further treatment. After all of the instruments had undergone the treatments, they were carefully evaluated under magnification. In some cases corrosion was examined by scanning electron microscopy (SEM) with chemical analysis by energy dispersive X-ray analysis (EDXA).

Function and Cleaning

Calf's liver was purchased from a grocery store. Sheep blood in Alsever's was obtained from Remel (Kansas City, KS). Instruments showing damage were used on the calf's liver or dipped in blood and the accumulation of tissue or blood was noted. Then the instruments were subjected to protocol E for routine cleaning, examined under the microscope for debris, and Bradford's reagent was placed onto the spots of damage to detect residual protein.[11]

Corrosion Testing

Several specifications for surgical instruments call for corrosion testing with copper sulfate. ASTM publishes two versions of this method, both of which were used in these studies. Method A967 applies generally to stainless-steel parts, while method F1089 applies specifically to surgical instruments.

To test per ASTM A967,[12] the parts were swabbed and kept wet for 6 min with a solution of 0.7 wt % H_2SO_4 and 1.6 wt % $CuSO_4 \cdot 5H_2O$ in DW. They were then carefully rinsed and dried, taking care not to disturb copper deposits if present. The criteria for passing the test was that they shall not exhibit copper deposits. To test according to ASTM F1089,[13] parts were swabbed and kept wet for 6 min with a solution of 9.6 wt % H_2SO_4 and 3.8 wt % $CuSO_4 \cdot 5H_2O$ in DW. They were then rinsed thoroughly in tap water and vigorously cleaned to remove any nonadherent copper plating. To pass the test all surfaces should show no visual signs of copper plating except in serrations, teeth, locks, ratchets, braze junctions, or solder joints. Dulling of polished surfaces or copper plating at periphery of solution drops was not cause for rejection.

RESULTS

Instruments

Protocol A.

In general, autoclaving in NaOH more than once caused darkening of the instruments, especially in the closed portions of box joints, as shown with the instrument labeled 1 in Figure 1. Some of the Pakistani stainless-steel instruments became darkened as shown in Figure 2, while the titanium tweezers became very dark. This discoloration could not be scrubbed or easily polished off. There did not seem to be any change in function, and tissue or blood did not accumulate on the dark spots or the rainbow areas. Routine cleaning did not remove the darkening.

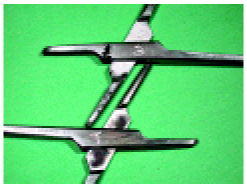

Figure 1. Jaws and box joints of two Mayo-Hager carbide-faced needle holders. The instrument on the top, labeled 3, was immersed in bleach for 1 h and shows severe corrosion. The lower instrument, labeled 1, was autoclaved five times in 1*N* NaOH and shows some mild discoloration on the outside of the box joint, and significant blackening in the inner surface of the box joint.
[Normal View 31K | Magnified View 135K]

Figure 2. Surgical scissors after protocol A, autoclaving five times in 1*N* sodium hydroxide for 1 h. The upper instrument was made in Germany, the lower instrument in Pakistan.
[Normal View 31K | Magnified View 141K]

Protocol B.

The five 1-h soaks in 1*N* NaOH caused corrosion on the carbon-steel tweezers and the steel spring on the Agricola tissue spreader and a slight discoloration of the titanium tweezers. There was no apparent damage to the other Roboz surgical instruments and they were bright and shiny. Some of the inexpensive clamps from VWR were slightly discolored, but this could easily be wiped off.

Protocol C.

Undiluted household bleach (5.25% or 6% sodium hypochlorite) caused pitting and other evidence of corrosion to many of the instruments, most notably at welds and carbide jaws, as shown on instrument 3 in Figure 1, and gold-coated handles as shown in Figure 3. Some of the Pakistani instruments showed no damage and some of the Roboz instruments did show damage as shown in Figure 4. Pitting on the inexpensive instruments was typically seen around the finger holes, welds, and scissor blades. The damage was evident after the first or second treatment. Those that showed damage got worse, but those that did not show damage after the second exposure did not show it after five exposures.

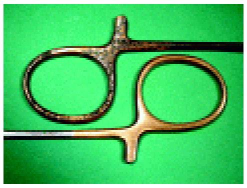

Figure 3. The gold-plated finger holes of the same needle holders shown in Figure 1. The upper instrument shows severe corrosive attack to the gold plating due to the bleach. The lower instrument shows no attack to the gold and only minimal discoloration of the stainless steel after autoclaving in sodium hydroxide.
[Normal View 34K | Magnified View 147K]

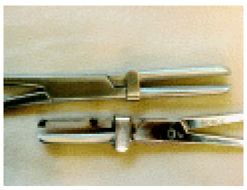

Figure 4. Tube occluding clamps after protocol C, soaking five times for 1 h in chlorine bleach. The upper instrument was made in Germany, the lower instrument in Pakistan.
[Normal View 30K | Magnified View 125K]

Protocol D.

Instruments subjected to autoclaving in water showed slight dulling of the polish, and a hint of corrosion at the edge of the box joints. Instruments autoclaved in an empty pan showed no damage.

Protocol E.

Instruments subjected to routine cleaning also showed some damage. The carbon-steel pick-ups rusted badly, the spring on a spreader rusted, and there were some rust spots on the scissors. This was observed after the first run and is probably a result of leaving the instruments wet on the bench top.

Cleaning

The localization of the tissue and blood was observed with low power microscopy and did not show unusual adherence to damaged areas. Observation after cleaning revealed no residual material. The use of Bradford's reagent did not identify protein residues.

Corrosion Testing

All instruments which were not damaged by the decontamination protocols passed both copper sulfate tests. However, some of those showing damage also passed. Some of the damage-prone areas passed A967 but only marginally passed F1089, most notably the spring of the Agricola spreader, the screw in the scissors, and the welded U-guide of the tubing clamps.

Neuroelectrodes

The room temperature soaks in 1*N* NaOH (protocol B) did not appear to harm the electrodes when examined with low power magnification. Functional testing was not within our capabilities; such testing would be important for the user of such electrodes. The treatment in bleach (protocol C) showed some corrosion products after the first immersion. After the second immersion the solder joint was corroded away and the electrode tip and the connector were no longer one piece.

DISCUSSION

The protocols used in these studies were a worst case, in that no cleaning or rust inhibitors such as instrument milk were utilized between cycles. Furthermore, autoclaving in sodium hydroxide was done for 1 h rather than the recommended 30 min. The most notable damage was localized corrosion around box joints and carbide jaws and gold-coated handles. Figures 1 and 3 show the jaws and handles of two Mayo-Hager needle holders with carbide-faced jaws and gold-coated handles, both labeled *CE Stainless Germany*. These are examples of effects of a single soak in bleach (upper instrument) and autoclaving five times in sodium hydroxide (protocol A). Severe pitting corrosion due to bleach can be seen at box joint and adjacent to the carbide face off the holder labeled 3 in Figure 1. In contrast, the holder labeled 1 in Figure 1 shows the blackening effect of protocol A on the inner part of the box joint and a little discoloration outside the joint.

Figure 3 shows the severe pitting of the gold coating after a 1-h soak in bleach and the shiny appearance after autoclaving five times in sodium hydroxide (protocol A). Examination by SEM demonstrated deep localized pitting throughout the coated region. Chemical analysis by EDXA confirmed that there was gold in the coating. This degree of attack to the gold coatings was confirmed with several other expensive instruments. After a 1-h immersion in bleach, the devices would be surrounded by black corrosion products. This attack was seen even after soaking in a 1/10 dilution of bleach. The gold handles passed both copper sulfate corrosion tests.

Another device-related observation was that in some cases where the same instrument type was available labeled *Germany* and *Pakistan*, the latter tended to suffer more corrosion. An example of the differences seen with autoclaving in NaOH (protocol A) are shown in Figure 2. The upper instrument was labeled *Stainless Germany CE* and was bright and shiny. The photograph suggests there is some darkening of the blade near the hinge, but this is just an artifact of light reflection from a polished surface. The lower scissor, labeled *S.S.PAKISTAN P*, had a very dark mottled discoloration.

Differences between German and Pakistani instruments were also seen after soaking in bleach. Figure 4 shows a typical comparison after five 1-h soaks in bleach (protocol C). The upper tube occluding clamp, labeled *Stainless Germany CE*, had a matte finish and was unchanged after treatment. This instrument also fully passed the ASTM F1089 corrosion test. The lower clamp, labeled *STAINLESS PAKISTAN*, showed severe pitting or perhaps crevice corrosion at the junction of the U-guide. During the ASTM F1089 test, copper plating occurred near the U-guide, but because the plating scrubbed off, the clamp still technically passed the test. The Pakistani instrument also showed corrosion of the jaw (visible in Figure 4, 7 mm away from the weld) and crevice corrosion inside the box joint (not visible in the figure).

Much of the damage from autoclaving in NaOH was cosmetic and would not affect the performance or cleaning of the instruments. Autoclaving in sodium hydroxide caused blackening in the closed portions of the box joints as shown in Figure 1. This could have been minimized if the box joints had been opened. Other instruments showed some diffuse darkening. Of note was the significant discoloration to the titanium tweezers. This effect of hot alkali treatment has been utilized in surface modification of titanium implants.[14]

Soaking in NaOH had the least effect on instruments of all the WHO methods tested. Only the carbon-steel tweezer and the coil spring of the Agricola spreader were damaged by room temperature 1*N* NaOH. The carbon-steel tweezer was included in these studies as a positive control. It is of interest that a 30-min immersion in 1.3*N* NaOH at 71°C to 80°C is a recommended step for neutralizing nitric acid used for passivation in the manufacturing of the type of stainless steels used for surgical instruments.[12] Thus, it is to be expected that these stainless steels are resistant to sodium hydroxide.

Immersion in sodium hypochlorite bleach did cause severe damage to some instruments. Stainless steel adjacent to carbide jaws on needle holders (Figure 1) was severely corroded and would have been functionally weaker, as would the spring on the Agricola spreader. Instruments with gold-coated handles suffered severe corrosion of the coating (Figure 3) as well as elsewhere. These instruments were clearly not reusable. However, many of the inexpensive Pakistani instruments suffered minimal damage after decontamination in bleach. It should be noted that the commercial bleach used was changed from 5.25% to 6% sodium hypochlorite during the course of these studies. Both concentrations meet the WHO guidelines of 20,000 ppm available chlorine. However, one must insure that chlorine-free bleach solutions are not used for these decontamination protocols.

Copper sulfate corrosion testing did not always predict which instruments would be damaged by decontamination. Although a failure or a marginal pass was a good indicator that damage was likely, as with the spreader spring, a pass did not necessarily mean damage would not occur. Besides this lack of sensitivity, the copper sulfate tests have several other limitations. Some of the locations on the instruments that are most likely to be damaged by the decontamination protocols (e.g., joints) are exempt from ASTM F1089. Additionally, copper sulfate tests mostly serve to verify that the steel surface is passivated and do not address or predict chloride attack (as by bleach). For example, the gold handles that corroded badly in bleach passed both tests. Another limitation of the copper sulfate tests is that they only apply to certain specific types of stainless steels. The ASTM F899 standard for stainless steels used for surgical instruments includes specifications for a wide range of alloys to meet the range of properties necessary for instruments.[15] However, because surgical instrument suppliers rarely specify the exact alloy used (and sometimes more than one alloy may be used for identical instruments), it is difficult to determine whether the copper sulfate tests are applicable to a particular instrument.

Surgical instruments are manufactured with stainless-steel alloys which conform to chemical and mechanical requirements of ASTM F899[15] and ISO standard 7153-1.[16] The differences seen between different instruments, in terms of susceptibility to corrosion in chlorine bleach, could be attributable to small differences in chemical composition, or to mechanical cold working during manufacturing. In discussing these issues with staff at laboratories that do chemical analysis of instruments, it became clear that chemical analysis of the instruments in this study would probably not provide much insight. Hardness testing was conducted on many instruments, and no deviation from specifications was observed. Therefore, it remains incumbent on the instrument users to establish how their particular instruments will be affected by these decontamination protocols.

The results of this study indicate that some of the protocols recommended by WHO and CDC[2][3] may cause damage to the instruments. This study did not allow us to predict exactly which individual instruments would be damaged. In general, inexpensive carbon-steel instruments are easily damaged, gold plating is damaged by bleach, and soldered and welded joints are attacked by bleach. Autoclaving in sodium hydroxide caused some discoloration, but its use requires care and special containment pans and lids[10] to avoid damage to autoclaves or personnel. Of the three, soaking in sodium hydroxide produced the least amount of damage to instruments.

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